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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/367,052	08/06/1999	TADAMITSU KISHIMOTO	1422-386PCT	3818

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/367,052

Applicant(s)

KISHIMOTO ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 16, 22 and 27-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 16, 22 and 27-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. Currently, claims 13, 16, 22, 27-34 are pending in the application.
2. In the Final Action mailed on February 23, 2005, claims 13, 16, 22, and 24-35 were pending and rejected. In response, the Applicant submitted an After-Final Amendment on July 25, 2005 amending claims 13, 16, 22, 27-30, 32, and 33; and canceling claims 24-26. In an Advisory action mailed on August 11, 2005, the After-Final amendment was permitted entry into the application, and several rejections were withdrawn on the basis of the entry.
3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 25, 2005 has been entered.

Claim Objections

4. **(Prior Objection- Withdrawn)** Claims 13, 16, and 22 were objected to because of the following informalities: the claims refer to the HIV-1 envelope protein (glycoprotein) by its abbreviation "env" without first identifying it by its complete name. The amendments of the After-Final amendment have overcome the objection. It is therefore withdrawn.

Claim Rejections - 35 USC § 101

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5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. **(New Rejection)** Claims 16, 22, 29, 30, and 32-34 are rejected under 35 U.S.C. 101

because the claimed invention is directed to non-statutory subject matter. These claim read on recombinant cells comprising a polynucleotide. However, the claims do not require that the cells are isolated, and thus read on human beings comprising such cells. It is suggested that the claims read on “isolated” recombinant cells.

Claim Rejections - 35 USC § 112

7. **(Prior Rejection- Withdrawn)** Claims 13, 16, 22, 24, 25, 27-35 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it was not known what activities fall within the scope of “an activity of a receptor capable of binding to a murine PBSF/SDF-1.” As indicated in the Advisory Action, this rejection was withdrawn in view of the amendments in the After-Final of July 2005.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. **(Prior Rejection- Maintained)** Claims 13, 16, 22, 24-27, 29, 31, 32, 34, and 35 were rejected in the Final action under 35 U.S.C. 112, first paragraph, as failing to comply with the

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written description requirement. The amendments to the claims have been considered but do not overcome the rejection of claims 13, 16, 22, 31, or 34 for the reasons indicated in the Advisory Action. I.e., while the claims remove reference to nucleotides comprising one of more deletion, addition, or substitutions, they do still read on any nucleotide that hybridizes to the complement of SEQ ID NO: 1, which would include nucleotides comprising one or more deletions, additions, or substitutions affecting the sequence of the encoded polypeptide. As no additional arguments have been presented by the Applicant with respect to the claims, the rejection is maintained against claims 13, 16, 22, 31, or 34.

The rejection was withdrawn from pending claims 27, 29, and 32 in the Advisory action. Further, the Advisory action also noted that an amendment of the claims to require that the nucleotide sequence that hybridizes to the complement of SEQ ID NO: 1 would be allowable if limited to sequences isolated from murine cells.

10. **(Prior Rejection- Maintained)** Claims 13, 16, 22, 24-27, 29, 31, 32, 34, and 35 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions comprising the full sequence of SEQ ID NO: 1, does not reasonably provide enablement for embodiments comprising only fragments of or comprising derivatives of the sequence that encode polypeptide capable of binding to murine PBSF/SDF-1. In the Advisory Action, the rejection was withdrawn from pending claims 27, 29, and 32. However, the rejection was maintained against 13, 16, 22, 31, and 34 because these claims still read on derivatives of SEQ ID NO: 1 (as described above and in the Advisory Action).

It is noted that the Advisory action also indicated that an amendment of claims to require that the nucleotide sequence that hybridizes to the complement of SEQ ID NO: 1 would be allowable if limited to sequences isolated from murine cells.

11. **(Prior Rejection- Withdrawn)** Claims 22, 26, 32, 34, and 35 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while potentially being enabling for a kit for the detection of HIV-1 infection comprising a cell transfected with a polynucleotide encoding CXCR-4 and CD4, does not reasonably provide enablement for a kit for the detection of the onset of AIDS, or for kits for detecting HIV infection wherein the cells express CD4, and only a portion of the CXCR-4 receptor that binds to murine PBSF/SDF-1. In view of the amendments of the After-Final amendment, the rejection is withdrawn either as resolved, or in favor of the rejections in paragraphs 7 and 8 above.

12. **(Prior Rejection-Withdrawn)** Claims 16, 25, 29, and 30 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for cells recombinantly expressing hCD4 and mCXCR-4 that may be infected with T-cell-line-tropic HIV, does not reasonably provide enablement for any cell expressing hCD4 and mCXCR-4 and which may be infected by any HIV when contacted therewith. As indicated in the Advisory Action, this rejection was withdrawn in view of the limitation of the claims to embodiments wherein the hCD4 and mCXCR-4 are both heterologous to the cell.

13. **(Prior Rejection- Withdrawn)** Claims 13, 16, 22, 24-35 were rejected was under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. As indicated

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in the Advisory Action, the amendments to the claims in the After-Final amendment have overcome these rejections.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

15. **(Prior Rejection- Maintained)** Claims 13, 24, 25, 27-30, and 35 were rejected under 35 U.S.C. 102(a) as being anticipated by Nagasawa et al., PNAS 93: 14725-29 (of record in the IDS of August 6, 1999). Claims 24, 25, and 35 have been cancelled from the application. The rejection is therefore withdrawn from these claims. Claims 29 and 30 (through their dependence from claim 16) have been amended to require the presence of heterologous hCD4 and mCXCR-4. The rejection is therefore withdrawn from these claims as well.

However, as was indicated in the Advisory Action, each of claims 13, 27, and 28 require only the expression of the murine CXCR-4 gene in a transformed cell. Such a method is disclosed in the Nagasawa reference. Thus, while claims drawn to methods of producing the cells of claims 16 and 22 (and their dependent claims) may be allowable over the art, the present methods of claim 13, 27, and 28 are anticipated by the teachings of Nagasawa.

16. **(Prior Rejection- Withdrawn)** Claims 13, 16, 24, 25, 28, 30, and 35 were rejected under 35 U.S.C. 102(a) as being anticipated by either of Heesen et al. (supra), or Ashorn et al., J Virol

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64: 2149-56. The rejection is withdrawn from claims 16, 24, 25, 30, and 35 for the reasons indicated in the Advisory Action. However, the claims are also drawn to cells that comprise an expression vector encoding the murine CXCR-4 receptor. While Heesen and Ashorn teach cells transformed with vectors encoding human CD4, and cells expressing murine CXCR-4, the references do not appear to teach cells transformed with a vector encoding murine CXCR-4. See e.g., page 5456-5457 (identifying cells that express the murine protein, but which appear to do so homologously, and not by transformation with an expression vector). The rejection is therefore withdrawn.

Conclusion

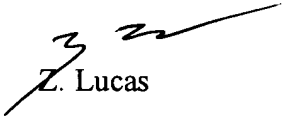
17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas

Patent Examiner



9/6/05
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